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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,260	07/22/1999	ROBERT L. CAMPBELL	P3250	2590

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EXAMINER

PRASTHOFFER, THOMAS W

ART UNIT

PAPER NUMBER

1627

DATE MAILED: 01/15/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/359,260

Applicant(s)

CAMPBELL ET AL.

Examiner

Thomas W Prasthofer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 74 and 76-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 74, 76-78, 80-92, 94 and 95 is/are rejected.
- 7) ☒ Claim(s) 79 and 93 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Detailed Action

Status of the Application

Receipt is acknowledged of a response to a notice of non-responsive amendment on 19 October 2001 (Paper No. 12).

Status of the Claims

Claims 74 and 76-95 are pending in the present application. The examiner notes that, on page 6 of the June 20, 2001 response to the non-final office action (Paper No. 10), applicant states that claims 75 and 85 have been cancelled (second line under III.). The examiner has not found an amendment on record that cancels claim 85.

Withdrawn Rejections

1. All of the outstanding rejections of claims 74-95 are hereby withdrawn.

Objections to the Claims

2. Claims 79 and 93 are objected to because they depend from rejected claims.

Claims Rejections – 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 74, 76-78, 80-86, and 91 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. In claims 74, 76, 80, 83, 84, and 86 the term “*whole molecule parameter*” is not defined by the specification in such a way that one of ordinary skill in the art would be able to determine the metes and bounds of the claimed invention. Page 28, lines 2-7 indicates that a “*whole molecule parameter*” is “*a value that characterizes a molecule irrespective of the arrangement of its constitutive atoms.*” With respect to peptides, the example is given that a whole molecule parameter “*is one that does not depend on the order or sequence of amino acids in the peptide.*” It is not clear if a “*whole molecule parameter*” can be a tag or identifier of some kind or if it is a parameter in some way linked to the structure of a molecule (peptide). For example, the molecular weight of a peptide depends on the sequence of the peptide and, based upon the specification, molecular weight, total dipole moment, and hydrophobicity, for example, would not be considered “*whole molecule parameters*” because these parameters do depend on the sequence of the peptide (G-D-E vs. W-F-Y, for example). Clarification is requested.

B. In claims 74 and 82 the term “*space filling technique*” is not defined by the specification in such a way that one of ordinary skill in the art would be able to determine the metes and bounds of the claimed invention. Page 10, lines 6-16 of the specification provides examples of space filling designs (not techniques) and does not provide a definition of either “*space-filling design*” or “*space-filling technique.*” If a first library were all possible pentamers and the second library were all possible tetramers with glycine at the N-terminus, for example, would the second library have been selected based upon a space-filling design? Clarification is requested.

C. In claims 74 and 77, the term “*test requirement*” does not appear to be linked to chemical, biological, or physiological functions, for example, and would appear to include “test requirement(s)” such as having a particular molecular weight, solubility in water, cost of synthesis, etc. Clarification is requested.

D. In claims 74, 76, and 80 the phrase “*determining a relationship*” includes the relative term “*relationship*” which renders the claim indefinite. A “relationship” may be direct, inverse, or may encompass the “relationship” of being independent. Clarification is requested.

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E. In claim 74, the metes and bounds of the second peptide library are not clear. The claims recites that the plurality of second test peptides are "*expected*" to provide an indicia of an activity, based upon a relationship. It is not clear what criteria are to be included or excluded for "*expecting*" whether or not a second peptide library would include a peptide provides and indicia of an activity. Would peptide length alone be enough to "*expect*" or would sequence information be included? Would, for example, a second peptide library that contains 75% of the peptides of a first library be "*expected*" to provide an indicia because there is a greater than 50% chance that it will include the active peptides of the first library? Clarification is requested.

F. In claims 74, 76-78, 80, and 91, the term "*indicia*" does not provide one of ordinary skill in the art a means of determining the metes and bounds of the presently claimed invention. For example, are molecular weight, hydrophobicity, charge, and molecular formula included a "*indicia*?" Clarification is requested.

G. In claim 76, it is not clear what distinguishes between a "*parameter*" and a "*whole molecule parameter*" or if the two are interchangeable. Clarification is requested.

H. In claims 77 and 78, it is not clear how a "*range*" of "*indicia*" (values?) may be "*qualified*." Clarification is requested.

I. While applicant may be his or her own lexicographer, a term in a claim may not be given a meaning repugnant to the usual meaning of that term. See *In re Hill*, 161 F.2d 367, 73 USPQ 482 (CCPA 1947). The term "isomers" in claims 81 and 82 is used by the claims to mean peptides or compounds "*sharing common global characteristics*," while the art accepted meaning is compounds (peptides) "*sharing the same formula but having different properties*" (Zumdahl, Steven S., "Chemistry", 4th ed., Houghton Mifflin Company, 1997). On page 48 of the specification, lines 7-12, applicant defines "*compound isomers*" as "*the group of compounds sharing common global characteristics*" and gives two examples of how the term may apply to peptides. The term "*isomers*" is therefore defined in the specification as "*sharing common global characteristics*." This definition is repugnant to the usual meaning of that term.

J. In claims 81 and 82, the term "isomers" is not defined by the specification in such a way that one of ordinary skill in the art would be able to determine the metes and bounds of the claimed invention. The term is defined in the specification as "*the group of compounds sharing*

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common global characteristics" but one of ordinary skill in the art would not know what the metes and bounds of "*global characteristics*" are.

K. In claim 85, it is not clear if applicant intended to recite "*whole molecule parameter*" rather than "*parameter*." If the claim is recited applicant's intended language, it is not clear what distinguishes a "*parameter*" from a "*whole molecule parameter*." Clarification is requested.

Claims Rejections – 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 74, 81, 87- 90, and 94 are rejected under 35 U.S.C. 102(b) as being anticipated by Tenson et al., The Journal of Biological Chemistry, 272:17425-17430, 1997 (Tenson et al.).

The Tenson et al. reference discloses each of the method steps of claim 74 (page 17427, left column). The ability of bacterial colonies to grow erythromycin containing agar plates reads on the claimed indicia of an activity of a plurality of first test peptides. Peptide length reads on the claimed relationship between measured indicia and whole molecule parameter. The ability of colonies to grow on erythromycin containing culture media plates reads on the claimed determining a test requirement relating to the measured first indicia. A second test peptide library containing pentapeptides reads on the claimed identifying a second test peptide library based on the relationship between peptide length and the ability to confer erythromycin resistance. The second library was a 5-codon library that was designed to express all possible pentapeptides (i.e. a space filling technique was used). Consequently, present claim 74 is anticipated by the reference

By not expressing and screening all possible 21-mer peptides, Tenson et al. anticipates defining a first test peptide library by representing each of a plurality of groups of peptides as isomers from a first peptide space as a representative candidate peptide (present claim 81).

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Approximately 10^5 different peptides (21-mers or less, because stop codons were randomly present in the coding sequence) were screened whereas the total number of possible peptides is far greater. See page 17427, first paragraph of the reference.

Tenson et al. disclose peptides that confer erythromycin resistance by their ability to bind to ribosomes which are receptors for elongation and termination factors and other regulatory molecules, anticipating present claim 87. Tenson et al. discloses the ability to bacteria expressing the peptides to grow in the presence of erythromycin anticipating present claim 88.

Inhibiting cell lysis in the presence of erythromycin reads on the claimed inhibition or prevention of a biological activity, anticipating present claim 89. Tenson et al. anticipates claim 90 because the E.coli cultured in vitro reads on the claimed cell cultured in vitro. Claim 94 is anticipated because the amino acid length of the disclosed peptides includes peptides within the range of 5-mers through 20-mers.

5. Claims 74, 92, 94, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Ostrem et al, Biochemistry 37:1053-1059 (1998).

The Ostrem et al. reference discloses each of the method steps of present claim 74. The ability of test peptides to bind to factor Xa reads on the claimed measuring indicia of an activity of a plurality of first test peptides (page 1054 first paragraph and page 1055 second paragraph). Determining a peptide length of 8 amino acids reads on the claimed determining a relationship between the measured first indicia of the activity and at least one whole molecule parameter of the plurality of first test peptides (page 1053, last paragraph). An assay of factor Xa activity reads on the claimed determining a test requirement relating to the first measured indicia (page 1054, first paragraph). Identifying a subset of the first peptide library and, based upon their ability to bind factor Xa, using the peptides in a prothrombinase assay reads on the claimed identifying a second test peptide library (page 1055, table 1 and figure 1). The authors also synthesized derivitized peptides and assayed them in coagulation assays (figure 5, page 1057). All resynthesized peptides of the second peptide library included specific amino acid motifs (the selection of peptides as well as modified peptides including the YIR sequence was a "*space-filling technique*" because the structures around the YIR sequence were replaced by a variety of moieties).

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Factor Xa acts both as a protease and as a receptor for factor Va and so reads on the claimed activity is inhibition or prevention of activation of a receptor (page 1053, first paragraph), anticipating present claim 92.

The first and second libraries of octameric peptides anticipate present claims 94 and 95.


6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Thomas Prasthofer** at telephone number **(703) 308-4548**. The examiner can normally be reached on Monday, Tuesday, Friday, and Saturday 8:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jyothsna Venkat can be reached on (703) 308-2439. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2742.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist at (703) 308-1235.

Thomas Prasthofer, Ph.D.

January 14, 2002


PADMASHRI PONNALURI
PRIMARY EXAMINER
for SPE